



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan et al

Serial No. 10/764,393

Filed: January 23, 2004

Title: NOVEL DYE LABELING COMPOSITION

Group Art Unit: Not yet known

Examiner: Not yet determined

527 Madison Avenue, 9th Floor
New York, New York 10022
March 8, 2004

FILED VIA EXPRESS MAIL

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.56 & 1.971.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following ninety-two (92) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

03/11/2004 EAREGAY1 00000035 051135 10764393
01 FC:1806 180.00 DA

Stavrianopolous, et al

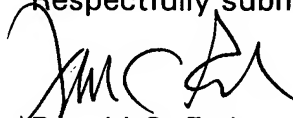
Serial No.: 10/764,393

Filed: January 23, 2004

Page 11 [Information Disclosure Statement – March 8, 2004]

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus

Registration No. 32,567

Natalie Bogdanos

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Stavrianopolous, et al

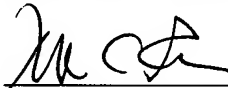
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Page 2 [Information Disclosure Statement – March 8, 2004]

PRIORITY FIRST CLASS MAIL CERTIFICATE

I hereby certify that this paper and any attachments herein are being deposited on the date below with the United States Postal Service as Priority First Class mail to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Ronald C. Fedus
Reg. No. 32,567

MAR 8 2004

Date

1. Ball, et al., "The use of tailed octamer primers for cycle sequencing," Nucl. Acids. Res. 26:5225-5227 (1998) [Exhibit 1];
2. Baranov, et al., "A new technique for the characterization of long-range tertiary contacts in large RNA molecules: insertion of a photolabel at a selected position in 16S rRNA within the Escherichia coli ribosome," Nucl. Acids Res. 25:2266-2273 (1997) [Exhibit 2];
3. Barany, et al., U.S. Patent No. 5,494,810, filed November 22, 1994 [Exhibit 3];
4. Bellhouse, et al., U.S. Patent No. 6,004,286, filed September 18, 1998 [Exhibit 4];
5. Bieniarz, et al., U.S. Patent No. 5,582,984, filed June 29, 1994 [Exhibit 5];
6. Bieniarz, et al., U.S. Patent No. 5,599,932, filed June 5, 1995 [Exhibit 6];
7. Bronstein, I.Y., U.S. Patent No. 4,978,614, filed July 20, 1989 [Exhibit 7];
8. Coassin, et al., U.S. Patent No. 5,462,854, filed April 19, 1993 [Exhibit 8];
9. Cros, et al, U.S. Patent No. 5,849,480, filed March 16, 1995 [Exhibit 9];
10. Dale, R.M., et al., "Direct covalent mercuriation of nucleotides and polynucleotides," Biochemistry 14:2447-2457 (1975) [Exhibit 10];
11. Dale, R.M., et al., "The synthesis and enzymatic polymerization of nucleotide containing mercury: potential tools for nucleic acid sequencing and structural analysis," Proc. Natl. Acad. Sci. USA 70:2238-2242 (1973) [Exhibit 11];
12. Doan, T.L., et al., "Targeted cleavage of polynucleotides by complementary oligonucleotides covalently linked to iron-porphyrins," Biochemistry 25:6736-6739 (1986) [Exhibit 12];
13. Eglinton, G., et al., "A coupling of acetylenic compounds," Adv. Organic Synthesis 4:225-328 (1963) [Exhibit 13];
14. Engelhardt, et al., U.S. Patent No. 4,894,325, filed January 15, 1987 [Exhibit 14];

15. Engelhardt, et al., U.S. Patent No. 5,241,060, filed June 4, 1990
[Exhibit 15];
16. Engelhardt, et al., U.S. Patent No. 5,288,609, filed October 30, 1992
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17. Engelhardt, et al., U.S. Patent No. 6,221,581, filed June 6, 1995
[Exhibit 17];
18. Engelhardt, et al., U.S. Patent Application No. 08/182,621, filed January 13, 1994, abandoned in favor of continuing application 09/302,816, filed March 31, 1998, and divisional applications 09/302,818, filed February 3, 1998 and 09/302,817, filed April 16, 1999; specification published in related European Patent Application No. 0 667 393, published August 16, 1995 enclosed herein [Exhibit 18];
19. Enzo Biochem, Catalog Nos. 42722, 4723, 4724, New York, NY
[Exhibit 19];
20. Ernst, et al., "Cyanine dye labeling reagents for sulfhydryl groups,"
Cytometry 10:3-10 (1989) [Exhibit 20];
21. Forgione, et al., U.S. Patent No. 4,375,972, filed December 7, 1981
[Exhibit 21];
22. Fuhrop, J.H., et al., Chapter 19 in "Porphyrins and Metalloporphyrins," ed.
Smith, K.M., Elsevier Science, New York (1975) [Exhibit 22];
23. Gelfand, et al., U.S. Patent No. 5,210,015, filed August 6, 1990
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24. Gemen, B., U.S. Patent No. 6,338,954, filed August 24, 2000 [Exhibit 24];
25. Glazer, A., et al., U.S. Patent 5,646,264, filed January 23, 1995
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26. Haces, A., U.S. Patent No. 5,248,618, filed June 5, 1991 [Exhibit 26];
27. Hamby, et al., U.S. Patent No. 5,730,849, filed September 30, 1996
[Exhibit 27];

28. Heller, et al., European Patent Application No. 0 070 685, published January 26, 1983 [Exhibit 28];
29. Hendrix, J.L., U.S. Patent No. 4,707,454, filed February 16, 1984 [Exhibit 29];
30. Hendrix, J.L., U.S. Patent No. 5,464,741, filed October 8, 1993 [Exhibit 30];
31. Higuchi, R.G., U.S. Patent No. 5,994,056, filed May 2, 1991 [Exhibit 31];
32. Hobbs Jr., et al., U.S. Patent No. 5,047,519, filed June 12, 1987 [Exhibit 32];
33. Impraim, et al., U.S. Patent No. 6,228,578, filed January 18, 1994 [Exhibit 33];
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35. Kahn, et al., U.S. Patent No. 5,948,648, filed May 29, 1998 [Exhibit 35];
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37. Kuhlmann, K.F., et al., "Synthesis, DNA-binding and biological activity of a double intercalating analog of ethidium bromide," Nucl. Acids. Res. 5:2629-2633 (1978) [Exhibit 37];
38. Kwok, et al., U.S. Patent No. 5,945,283, filed December 17, 1996 [Exhibit 38];
39. Larock, "Organomercurials in Organic Synthesis," Tetrahedron 38:1713-1754 (1982) [Exhibit 39];
40. Lee, L.G., et al., "DNA sequencing with dye-labeled terminators and T7 DNA polymerase: effect of dyes and dNTPs on incorporation of dye-terminators and probability analysis of termination fragments," Nucl. Acids Res. 20:2471-2488 (1992) [Exhibit 40];

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43. Liu, H., et al., "PCR amplification using deoxyinosine to replace an entire codon and at ambiguous positions," Biotechniques 16:24-26 (1994) [Exhibit 43];
44. Liu, D., et al., "Stable human immunodeficiency virus type 1 (HIV-1) resistance in transformed CD4+ monocytic cells treated with multitargeting HIV-1 antisense sequences incorporated into U1 snRNA," J. Virol 71:4079-4085 (1997) [Exhibit 44];
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46. Loakes, D., et al., "5-Nitroindole as an universal base analogue," Nucl. Acids Res. 22:4039-4043 (1994) [Exhibit 46];
47. Loakes, D., "The applications of universal DNA base analogues," Nucl. Acids Res. 29:2437-2447 (2001) [Exhibit 47];
48. Malek, et al., U.S. Patent No. 5,130,238, filed August 23, 1989 [Exhibit 48];
49. Maulding, D.R., et al., "Chemiluminescence from Reactions of Electrophilic Oxamides with Hydrogen Peroxide and Fluorescent Compounds," J. Org. Chem. 33:250-254 (1968) [Exhibit 49];
50. Moan, J., et al., "Porphyrin photosensitization and phototherapy," Photochem. Photobio. 43:681-690 (1986) [Exhibit 50];
51. Mujumdar, R.B., et al., "Cyanine dye labeling reagents containing isothiocyanate groups," Cytometry 10:11-19 (1989) [Exhibit 51];
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58. Rabbani, E., et al., U.S. Patent Application No. 09/896,897, filed June 30, 2001; specification published in related European Patent Application No. 1 275 737, published January 15, 2003 [Exhibit 58];
59. Rabbani, E., et al., U.S. Patent Application No. 10/096,076, filed March 12, 2002; specification published in related European Patent Application No. EP 1 344 835, published September 17, 2003 enclosed herein [Exhibit 59];
60. Randall, M.H., et al., U.S. Patent No. 6,114,350, filed April 19, 1999 [Exhibit 60];
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66. Schaap, et al., "Chemical and Enzymatic Triggering of 1,2-Dioxetanes. 1: Aryl Esterase-Catalyzed Chemiluminescence from a Naphthyl Acetate-Substituted 1,2-Dioxetane," Tetrahedron Letters 28:935-938 (1987) [Exhibit 66];

67. Schaap, A.P., et al., "Chemical and Enzymatic Triggering of 1,2-Dioxetanes. 3: Alkaline Phosphatase-Catalyzed Chemiluminescence from an Aryl Phosphate-Substituted Dioxetane," Tetrahedron Letters 28:1159-1163 (1987) [Exhibit 67];
68. Selinger, D.W., et al., "RNA expression analysis using a 30 base pair resolution *Escherichia coli* genome array," Nature Biotech. 18:1262-1268 (2000) [Exhibit 68];
69. Shibahara, S., et al., "Site-directed cleavage of RNA," Nucl. Acids Res. 15:4403-4415 (1987) [Exhibit 69];
70. Singer, et al., U.S. Patent No. 6,323,337, filed May 12, 2000 [Exhibit 70];
71. Southwick, P.L., et al., "Cyanine dye labeling reagents – carboxymethylindocyanine succinimidyl esters," Cytometry 11:418-430 (1990) [Exhibit 71];
72. Stavrianopolous, et al., U.S. Patent No. 4,868,103, filed February 19, 1986 [Exhibit 72];
73. Stavrianopolous, et al., U.S. Patent No. 4,952,685, filed April 28, 1987 [Exhibit 73];
74. Stavrianopolous, et al., U.S. Patent No. 4,994,373, filed July 20, 1989 [Exhibit 74];
75. Stavrianopolous, et al., U.S. Patent No. 5,013,831, filed May 8, 1990 [Exhibit 75];
76. Talaat, A.M., et al., "Genome-directed primers for selective labeling of bacterial transcripts for DNA microarray analysis," Nature Biotech. 18:679-682 (2000) [Exhibit 76];
77. Tao, et al., "Genomics: Expression Analysis of *Escherichia coli* Growing on Minimal and Rich Media," J. Bact. 181:6425-6490 (1999) [Exhibit 77];
78. Trulson, et al., U.S. Patent No. 5,578,832, filed September 2, 1994 [Exhibit 78];

79. Urdea, et al., U.S. Patent No. 5,132,204, filed May 31, 1989 [Exhibit 79];
80. Van Gelder, et al., U.S. Patent No. 5,891,636, filed September 3, 1997 [Exhibit 80];
81. Waggoner, et al., U.S. Patent No. 5,268,486, filed May 15, 1992 [Exhibit 81];
82. Waggoner, et al., U.S. Patent No. 5,627,027, filed September 22, 1992 [Exhibit 82];
83. Waggoner, et al., U.S. Patent No. 6,008,373, filed June 7, 1995 [Exhibit 83];
84. Walker, et al., U.S. Patent No. 5,270,184, filed November 19, 1991 [Exhibit 84];
85. Walker, et al., U.S. Patent No. 5,455,166, filed January 9, 1992 [Exhibit 85];
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87. Wieringa, J.H., et al., "Adamantylideneadamantane Peroxide. A Stable 1,2 Dioxetane," Tetrahedron Letters 2:169-172 (1972) [Exhibit 87];
88. Wittwer, et al., U.S. Patent No. 5,455,175, filed January 10, 1994 [Exhibit 88];
89. Wittwer, et al., U.S. Patent No. 6,174,670, filed June 4, 1997 [Exhibit 89];
90. Zhu, Z., et al., "Directly labeled DNA probes using fluorescent nucleotides with different length linkers," Nucl. Acids. Res. 22:3418-3422 (1994) [Exhibit 90];

The ninety (90) foregoing references (numbers 1-90) were cited in the specification of the instant application.

A completed Form PTO-1449 listing the 90 above-submitted documents is also attached hereto as Exhibit 91.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan et al

Serial No. 10/764,393

Group Art Unit: Not yet known

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TRANSMITTAL
INFORMATION DISCLOSURE STATEMENT

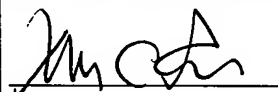
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

PRIORITY FIRST CLASS MAIL CERTIFICATE

I hereby certify that this paper and any attachments herein are being deposited on the date below with the United States Postal Service as Priority First Class mail to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Ronald C. Fedus
Reg. No. 32,567

MAR 8 2004
Date

Enz-61(D7)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
 - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
 - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.

[x] Charge the fee to Deposit Account No. 05-1135, Order No. **Enz-61(D7)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. [] 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. [] 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
 - c. [] The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. [] I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- [] I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Enz-61(D7)

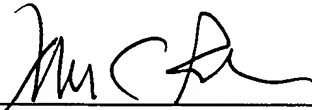
10. [] A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

[X] Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **Enz-61(D7)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

[x] The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: March 8, 2004

By: 
Ronald C. Fedus
Registration No. 32,567

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Enz-61(D7)

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

INFORMATION DISCLOSURE CITATION
(use several sheets if necessary)Atty. Docket No.
ENZ-61(D7)

Serial No. 10/764,393

Applicants: Ilan, et al

Filed: January 23, 2004

Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	5 4 9 4 8 1 0		Barany, et al			
	6 0 0 4 2 8 6		Bellhouse, et al			
	5 5 8 2 9 8 4		Bieniarz, et al			
	5 5 9 9 9 3 2		Bieniarz, et al			
	4 9 7 8 6 1 4		Bronstein, IY			
	5 4 6 2 8 5 4		Coassin, et al			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRAN- SLATION YES NO
EP	0 6 6 7 3 9 3	8/16/95	Rabbani et al	A1		
EP	0 0 7 0 6 8 5	7/14/82	Heller, et al	A1		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Ball, et al., "The use of tailed octamer primers for cycle sequencing," <u>Nucl. Acids. Res.</u> 26:5225-5227 (1998)
	Baranov, et al., "A new technique for the characterization of long-range tertiary contacts in large RNA molecules: insertion of a photolabel at a selected position in 16S rRNA within the Escherichia coli ribosome," <u>Nucl. Acids Res.</u> 25:2266-2273 (1997)
	Dale, R.M., et al., "Direct covalent mercuration of nucleotides and polynucleotides," <u>Biochemistry</u> 14:2447-2457 (1975)
	Dale, R.M., et al., "The synthesis and enzymatic polymerization of nucleotide containing mercury: potential tools for nucleic acid sequencing and structural analysis," <u>Proc. Natl. Acad. Sci. USA</u> 70:2238-2242 (1973)
	Doan, T.L., et al., "Targeted cleavage of polynucleotides by complementary oligonucleotides covalently linked to iron-porphyrins," <u>Biochemistry</u> 25:6736-6739 (1986)
	Eglinton, G., et al., "A coupling of acetylenic compounds," <u>Adv. Organic Synthesis</u> 4:225-328 (1963)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office INFORMATION DISCLOSURE CITATION (use several sheets if necessary)	Atty. Docket No. ENZ-61(D7)	Serial No. 10/764,393
	Applicants: Ilan, et al	
	Filed: January 23, 2004	Group: Not yet known

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	5 8 4 9 4 8 0		Cros, et al			
	4 8 9 4 3 2 5		Engelhardt, et al			
	5 2 4 1 0 6 0		Engelhardt, et al			
	5 2 8 8 6 0 9		Engelhardt, et al			
	6 2 2 1 5 8 1		Engelhardt, et al			
	4 3 7 5 9 7 2		Forgione, et al			
	5 2 1 0 0 1 5		Gelfand, et al			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRAN- SLATION YES NO
WO	9 9 2 8 5 0 0	11/27/98	Lee, et al			
EP	0 9 1 7 0 3 9	1/12/00	Rabbani, et al	A1		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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	Applicants: Ilan, et al	
	Filed: January 23, 2004	Group: Not yet known

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